

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of the effect of 808 nm low level laser on reversing the effect of inferior alveolar nerve block in 6-9 years old children

Protocol summary

Study aim

determining the effect of 808 nm low level laser on reversing the effect of inferior alveolar nerve block in 6-9 years old children

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, sealed envelopes were used for randomization.

Settings and conduct

34 children aged 6-9 years with decayed teeth, who are indicated for pulpotomy on both sides of the mandible and are systemically healthy, with Frankel cooperation level 3 and 4 are selected as samples. Inferior alveolar nerve block is applied to them and after performing the pulpotomy treatment and after 30 minutes of applying the laser block with a wavelength of 808 nm, a point in the anesthesia injection area is irradiated. The return of the anesthetic effect was measured by touching the area and by the child's statements, and its time was recorded. On the opposite side, the laser device is placed in the area without radiation, and as a control group, it is compared with the other side in terms of the return time of the anesthesia effect and the possibility of trauma caused by biting after 24 hours. Sealed envelopes were used to determine the order of the intervention.

Participants/Inclusion and exclusion criteria

- Children with scores of 3 and 4 based on Frankel's behavioral rating scale.
- Children aged 6 to 9 have the ability to understand and respond to soft tissue sensations.
- Patients who need pulpotomy treatment of left and right mandibular molars under inferior alveolar nerve anesthesia.

Intervention groups

experimental group: 808 nm laser control group: off mod laser

Main outcome variables

reversal of anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210914052474N2**

Registration date: **2023-01-04, 1401/10/14**

Registration timing: **prospective**

Last update: **2023-01-04, 1401/10/14**

Update count: **0**

Registration date

2023-01-04, 1401/10/14

Registrant information

Name

Fatemeh Shekarchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2217 5350

Email address

f.shekarchi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of 808 nm low level laser on reversing the effect of inferior alveolar nerve block in 6-9 years old children

Public title

the effect low level laser on reversing the effect of inferior alveolar nerve block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 6-9 years old without systemic disease Children with Frankel level 3 and 4 Patients who need pulpotomy of left and right mandibular primary molars under inferior alveolar nerve block.

Exclusion criteria:

history of sensitivity to anesthetics and sulfate errors in the injection of anesthesia during the study.

Age

From **6 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

More than 1 sample in each individual

Number of samples in each individual: **2**
mandibular primary molars

Randomization (investigator's opinion)

Randomized

Randomization description

The study was conducted in a split-mouth manner, and sealed envelopes were used for randomization. In this way, envelopes are first randomly selected to determine the side under laser radiation. Then envelopes are selected to determine the type of intervention (or control) in the first session.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patient is blinded by putting shield glasses on his/her eyes and thus he/she is unaware about the activation of the laser device. Result assessor is unaware about which method is used in the session and will only enters the pain score and so on he/she is blinded. The data is given to the analyzer by certain codes and he analyzes only the codes without knowing about their nature.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

no. 3, Nikkhu alley, Tabriziar ave., Mirdamad Blvd.

City

Tehran

Postal code

3413865761

Approval date

2022-11-14, 1401/08/23

Ethics committee reference number

IR.SBMU.DRC.REC.1401.059

Health conditions studied

1

Description of health condition studied

anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The duration of the anesthesia

Timepoint

45 minutes after injection and then every 10 minutes

Method of measurement

touching by a sharp object

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: low level laser konftec 808 nm 6.3 J, 23s on every point will be used on 12 point (6 point intra-oral and 6 point extra-oral) 45 minutes after block injection.

Category

Treatment - Devices

2

Description

Control group: off mod laser will be located on 12 points like intervention group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
dental school of shahid beheshti university
Full name of responsible person
Fateme Shekarchi
Street address
no.3 Tabrizian Avn., Mirdamad Blvd
City
Tehran
Province
Tehran
Postal code
3415642798
Phone
+98 21 2217 5350
Email
zahra_kia_ss@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti Dental School, Daneshjoo Blvd,
Velenjak
City
tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2203 2387
Email
Zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fateme Shekarchi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shahid Beheshti Dental school, Daneshjoo Blvd,
Velenjak
City
Tehran
Province
Tehran
Postal code
1234567891
Phone
+98 21 2217 5350
Email
zahra_kia_ss@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fateme Shekarchi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shahid Beheshti Dental school, Daneshjoo Blvd,
Velenjak
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2217 5350
Email
zahra_kia_ss@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fateme Shekarchi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Shahid Beheshti Dental school, Daneshjoo Blvd,
Velenjak

City

Tehran

Province

Tehran

Postal code

1234567899

Phone

+98 21 2217 5350

Email

zahra_kia_ss@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

the recorded data can be shared based on the studied indicators after identifying the samples individuals. these data include the numbers and scores reported from sensitivity to touch and trauma due to biting.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

researchers working in academic and scientific institutes can apply for access to data.

Under which criteria data/document could be used

performing statistical analysis to compare data with other studies this field is one of the conditions for access to data, so the analysis must be appropriate to the type of data received from the applicant.

From where data/document is obtainable

The applicant can apply for access to the data via email zahra_kia_ss@yahoo.com.

What processes are involved for a request to access data/document

after submitting the request by e-mail, the applicant will be able to access the information within one week after submitting the request, if has the request conditions.

Comments